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Client Matter No. 68030.0002.002
Atty. Docket No. LED0001 CON
Express Mail No. EV322530175US

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Appellants: Steven Lederman

Serial No.: 10/067,515

Art Unit: 1761

Filing Date: February 4, 2002

Examiner: Helen Pratt

Title: **HIGHLY SOLUBLE
NUTRITIONAL COMPOSITIONS
CONTAINING CALCIUM**

TRANSMITTAL OF APPELLANT'S BRIEF UNDER 37 CFR 1.192

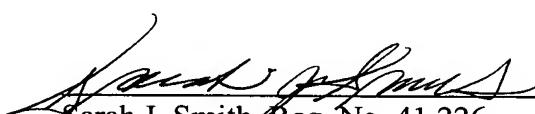
Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Please find enclosed an original and three copies of Brief for Appellant. Also, please find enclosed a check in the amount of \$640.00. Any fee deficiency associated with this submittal may be charged to Deposit Account No. 50-1123.

Respectfully submitted,

May 5, 2004
Date


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BRIEF FOR APPELLANT

To: Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In furtherance to the Notice of Appeal to the Board of Appeals filed December 5, 2003, in the above-referenced application, Appellant hereby submits this Brief for Appellant.

I. RELATED APPEALS AND INTERFERENCES

The undersigned legal representative of Appellant hereby confirms that there are no known appeals or interferences relating to the present application, or any parent application, which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

II. STATUS OF THE CLAIMS

Claims 21-60 are pending in the application. Claims 21-60 stand rejected under a Final Office Action dated November 5, 2003. Specifically, claims 21-60 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite, claims 21-27, 29, 31-32, 39, and 41-42 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Saleeb *et al.* (U.S. Patent No. 5,028,446), and claims 28, 30, 33-38, 40, and 43-60 were rejected under 35 U.S.C.

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§103(a) as being unpatentable over Saleeb *et al.* and further in view of Andon (U.S. Patent No. 5,468,506) and Keating (5,500,232). On December 5, 2003, Appellant appealed the final rejection by filing a Notice of Appeal of all pending claims 21-60. The pending claims on appeal are set forth in the Appendix hereto.

III. STATUS OF THE AMENDMENTS

No amendments have been filed subsequent to the final rejection of claims 21-60 in the pending application.

IV. SUMMARY OF THE INVENTION

The present invention relates to nutritional sources of solubilized calcium. More particularly, the present invention relates to sources of solubilized calcium having improved shelf life and stability. Minerals are an essential part of the human diet. Sufficient quantities of most minerals can be obtained through the proper choice of foods and beverages; however, many people do not consume a well balanced diet, and mineral supplements can be beneficial to many. Numerous attempts have been made to provide calcium nutritional supplements that are easily consumed by the public, are readily available, contain easily absorbable minerals, and have long storage times without degradation. However, none of the prior art addresses the issue of multiple mineral supplements in high levels that provide for a highly soluble, stable product with little or no taste or odor and which is essentially clear when reconstituted in water.

The present invention overcomes the deficiencies of the prior art by providing compositions comprising soluble bioavailable calcium and/or other minerals at a high concentration due to the high solubility attained through the processing method of this invention. The compositions of the present invention are powders that can be reconstituted in aqueous solutions, are more stable and have improved clarity, odor, taste, smell and texture.

More specifically, the present invention provides novel methods for producing mineral compositions, comprising: making an aqueous slurry containing calcium; fully solubilizing the aqueous slurry in an aqueous acid solution to produce a solution containing solubilized calcium; and producing a dried, readily solubilizable product having an amorphous structure by drying the solution containing solubilized calcium. The dried product has improved organoleptic properties adapted for incorporation in edible products and for enhanced rate of solubilization when reconstituted in aqueous solutions.

V. ISSUES

- A. Whether claims 21-60 are definite and particularly point out and distinctly claim the subject matter which Appellant regards as the invention.
- B. Whether claims 21-27, 29, 31-32, 39, and 41-42 are patentable under 35 U.S.C. §103(a) over Saleeb *et al.* (U.S. Patent No. 5,028,446).
- C. Whether claims 28, 30, 33-38, 40, and 43-60 are patentable under 35 U.S.C. §103(a) over Saleeb *et al.* and further in view of Andon (U.S. Patent No. 5,468,506) and Keating (5,500,232).

VI. GROUPING OF THE CLAIMS

All pending claims 21-60 are grouped together since they are believed to have respective common features, and thus common grounds for patentability.

Therefore, in the event the grounds asserted by Appellants for patentability of a group is not found by the Board of Patent Appeals and Interferences to sustain Allowability, then each of the claims within that grouping would fall, unless it depends from a claim that is found to be allowable on separate grounds.

VII. ARGUMENTS

A. Claims 21-60 are definite under 35 U.S.C. § 112, second paragraph

In the Final Office Action dated September 5, 2003, the Examiner rejected claims 21-60 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specially, the Examiner asserted that claims 21, 47, 57, and 59 are indefinite in the use of the phrase "amorphous structure" because the phrase "producing a dried, readily solubilizable product having an amorphous structure by drying said solution containing solubilized calcium" does not state what drying conditions make an amorphous structure. This rejection is respectfully traversed.

Although the precise mechanism by which the increased rate of solubilizing and long term stability of the products of the present invention are achieved are not known, it is believed that the substantially amorphous structure of the present invention is formed by the combination of method steps in which an aqueous calcium slurry is solubilized in a fully solubilized acid solution, thereby forming a solubilized complex. This solution, when dried sufficiently rapidly to maintain the bonds thus formed, results in a substantially amorphous

structure rather than a substantially crystalline structure. *See* Specification at page 20, lines 5-24.

Further, it is asserted that it is not necessary for the claims to recite the specific conditions required to obtain an amorphous solid. Rather, all that is necessary is to recite that an amorphous solid is produced upon drying. That is, any drying method that will produce an amorphous solid is included in the claims. It is well within the skill of persons skilled in the art to determine whether an amorphous solid has been produced after using a particular drying method.

It is asserted that the disclosure of the present application provides sufficient information to one of ordinary skill in the art to render the claims sufficiently definite. Withdrawal of this Section 112, second paragraph rejection is respectfully requested.

B. Claims 21-27, 29, 31-32, 39, and 41-42 are patentable under 35 U.S.C. §103(a) over Saleeb et al. (U.S. Patent No. 5,028,446).

In the final Office Action, the Examiner maintained the rejection of claims 21-27, 29, 31-32, 39, and 41-42 over Saleeb *et al.* (hereinafter "Saleeb") for reasons of record cited in the first Office Action dated April 1, 2003, and for additional reasons cited below. Specifically, in the first Office Action the Examiner asserted that Saleeb discloses making a slurry of fumaric acid and water and a calcium containing aqueous suspension under shear conditions at temperatures not over 160 °F and drying the mixture. The Examiner further asserts that the product is considered to contain solubilized calcium having improved organoleptic properties and enhanced rate of solubilization because the same process is used which would also make for an amorphous structure. In the final Office Action, the Examiner asserts that while claim 21 was amended to require that by fully solubilizing the aqueous slurry that a dried solubilized product having an amorphous structure is made by drying, Saleeb also fully solubilizes their aqueous solution containing calcium in an aqueous acid solution because they also mix ingredients as applicants do. The Examiner concludes that "nothing in the form of a showing has been shown that applicant's product is more amorphous than that of the reference, which only discloses 'generally crystalline,'" and therefore asserts that it would have been obvious to make a product which would be as amorphous as shown by the process of Saleeb.

This rejection is respectfully traversed. It is submitted that claims 21-27, 29, 32, 39, and 41-42 comprise distinguishing features which are neither taught nor suggested by the prior art.

Specifically, the claims of the present invention specifically recite the steps of first making an aqueous slurry containing calcium, then fully solubilizing the aqueous slurry in an aqueous acid solution to produce a solution containing solubilized calcium; and producing a dried, readily solubilizable product having an amorphous structure by drying said solution containing solubilized calcium. An example of a method for producing an amorphous structure as required by the claims is provided in the Specification, which states:

When a solid compound is formed from solution by slowly evaporating its water, the atoms of the compound arrange themselves into an ordered crystal structure, forming strong bonds among the solid's cations and anions. However, when a solid forms **rapidly**, the atoms of the compound are **unable to form an ordered crystal structure**, and the bonds among the solid's ions are weaker. **This non-crystalline solid is also known as an amorphous solid.**

Specification, page 20, lines 6-11 (emphasis added). Furthermore,

In the present invention, a regular crystal structure does not exist. Instead, the product is an amorphous solid. Figure 3 shows X-ray diffraction patterns for some of the compounds of this invention. These indicate that the present compounds are less crystalline (i.e., more amorphous) than the compounds in the prior art.

Specification, page 20, lines 12-16.

In contrast, Saleeb teaches a method for producing and using calcium fumarate, wherein the calcium fumarate formed according his method "has a generally crystalline structure" (col. 1, lines 63-64). Briefly, Saleeb teaches at col. 1, line 65 through col. 2, line 2 that the calcium fumarate is formed by

maintaining the order of addition of the reactants, controlling the processing parameters and using fairly large amounts of water. It has been found that since fumaric acid is almost insoluble in water, a slurry of water and fumaric acid is first formed.

Emphasis added. Further, Saleeb warns at col.2, lines 49-41 that

It has been found that the reaction and conditions of the reaction that affect crystal growth of the calcium fumarate need to be controlled.

Emphasis added. Further emphasizing the need for using large amounts of water in his process, Saleeb states at col. 2, lines 63-68 that

the high water level ensures crystallization from a dilute mixture that **propagates the crystal growth and perfection** of the resultant calcium fumarate products, and eliminates the formation of hardened masses that produce excessive fines (<400 mesh) on further grinding.

Emphasis added. Saleeb states at col. 3, line 68 through col. 4, line 2 that the reason for wanting a crystalline structure rather than a non-crystalline structure (i.e., an amorphous structure) is that

If the calcium fumarate is not a crystalline structure, then it is not readily soluble and tends to clump.

Emphasis added. Thus, Saleeb clearly did not teach or even suggest the preparation of an amorphous calcium product having improved organoleptic qualities and improved rate of solubilization. In fact, based on the above, Saleeb clearly teaches away from the production of an amorphous solid.

In order to prepare the crystalline composition Saleeb first prepares an acid slurry which is not fully solubilizable. *See* Saleeb, col. 2, lines 42-48. This is in contrast to the method of the present invention, which first prepares a calcium slurry, and then solubilizes the slurry in an aqueous acid solution.

In conclusion, Saleeb clearly teaches a different method than that recited in the presently pending claims. Saleeb requires that the steps be performed in a very specific order in order to ensure that a crystalline product is obtained. In contrast, the method of the present invention provides a process for ensuring that an amorphous structure is formed. Thus, the Examiner's conclusion that Saleeb teaches the same product is based on an erroneous understanding the Saleeb method. Accordingly, it is asserted that the methods and compositions of the present invention are novel and nonobvious in view of Saleeb, and withdrawal of this invention is respectfully requested.

C. Claims 28, 30, 33-38, 40, and 43-60 are patentable under 35 U.S.C. §103(a) over Saleeb *et al.* and further in view of Andon (U.S. Patent No. 5,468,506) and Keating (5,500,232).

In the final Office Action, claims 28, 30, 33-38, 40, and 43-60 were rejected under 35 U.S.C. § 102(a) over Saleeb as applied to claims 21-27, 29, 32, 39, and 41-42, and further in view of Andon and Keating for reasons of record cited in the first Office Action dated April 1, 2003. More specifically, the Examiner asserts that claim 28 further requires that the aqueous solution attain a temperature of at least 170 °F, and that Andon et al. disclose a process of making a nutritional mineral supplement containing calcium citrate malate by dissolving citric acid and malic acid in water, heating to 131 °F while stirring, then adding calcium carbonate which had been combined with water at a pH of 4.3, and then dried. The Examiner then asserts that raising the temperature as in claim 28 is seen as within the skill of the ordinary worker. Next, the Examiner asserts that Keating discloses that it is known to heat calcium compounds such as calcium glycerophosphate and calcium hydroxide at no heat, 60 and 68 °C, and also that the particular acid affects the solubility of the calcium. From this the Examiner concludes that it would have been obvious to heat the mixture in the process of Andon as Keating discloses that heating of certain calcium compounds improves their solubility. This rejection is respectfully traversed.

Claims 28, 30, 33-38, 40, and 43-46 depend either directly or indirectly from claim 26, and therefore contain all the patentably distinguishable features of the method of claim 26 as discussed above, including the distinguishing element of providing an amorphous product. Therefore, for the same reasons discussed above, claims 28, 30, 33-38, and 40 are also novel and nonobvious over Saleeb. Therefore, even if there were motivation to combine the teachings of Saleeb with the teachings of Andon and Keating, the combination would not teach the method or products of the present invention, since none of the cited references teaches a method of producing an amorphous solid.

With respect to claims 47-60, it is asserted that these claims are also novel and nonobvious in view of Saleeb for the same reasons as presented above. More specifically, Saleeb does not teach or suggest a method of producing an amorphous product, and in fact Saleeb actually teaches away from producing amorphous products since Saleeb states that amorphous solids are insoluble. And as stated above, even if there were motivation to combine the teachings of Saleeb with the teachings of Andon and Keating, the combination would not teach the method or products of the present invention, since none of the cited references teaches a method of producing an amorphous solid.

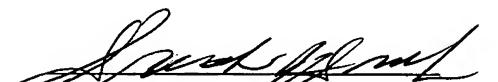
Based on the above arguments, it is asserted that claims 28, 30, 33-38, 40, and 43-60 are novel and nonobvious in view of Saleeb and further in view of Andon and Keating. Withdrawal of this rejection is respectfully requested.

VIII. CONCLUSION

In view of all of the above claims 21-60 are believed to be allowable and the case in condition for allowance and it is respectfully requested that the Examiner's rejections be overturned.

Respectfully submitted,

May 5, 2004
Dated



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Attorney Docket No. LED001 CON
Client/Matter No. 68030.0002.002

CLAIMS ON APPEAL

21. A method of making a powder for human or animal consumption having improved organoleptic qualities and improved rate of solubilization, comprising:

making an aqueous slurry containing calcium;

fully solubilizing said aqueous slurry in an aqueous acid solution to produce a solution containing solubilized calcium; and

producing a dried, readily solubilizable product having an amorphous structure by drying said solution containing solubilized calcium

wherein the product is adapted for human consumption in a form selected from the group consisting of

- (i) solubilized in an aqueous solution to produce solubilized calcium,
- (ii) a dried powder in granular form,
- (iii) a dried powder in tabular form,
- (iv) incorporated into a gum,
- (v) incorporated into pharmaceutical dose,
- (vi) incorporated into a beverage, and
- (vii) incorporated into a food.

22. The method of making a powder for human consumption according to claim 21, wherein the form of the product for human consumption selected is incorporated into a beverage and the beverage is selected from the group consisting of tea, fruit juice, carbonated drinks and sports drinks.

23. The method of making a powder for human or animal consumption according to claim 21, wherein the form of the product for human consumption selected is incorporated into a food and the food is selected from the group consisting of candy, gelatin products and puddings.

24. The method of making a powder for human or animal consumption according to claim 21, wherein the form of the product for human consumption selected is solubilized in

an aqueous solution to produce solubilized calcium and the method further includes the steps of:

solubilizing the dried compound having an amorphous structure in water to produce a drink containing solubilized calcium; and

packaging the drink in a sealed container,

wherein the drink in the sealed container has a shelf life of at least 6 months with the calcium remaining in solution for said at least 6 months.

25. The method of making a powder for human or animal consumption according to claim 24, wherein the form of the product for human consumption selected is incorporated into a beverage and the beverage is selected from the group consisting of tea, fruit juice, carbonated drinks and sports drinks.

26. A method of making a calcium containing product for subsequent consumption, comprising:

making an aqueous slurry containing calcium;

acidifying said aqueous slurry to produce an aqueous solution containing solubilized calcium while attaining a temperature of at least 130°F; and

producing a dried, readily solubilizable product having an amorphous structure by drying said solution containing solubilized calcium, said dried product having improved organoleptic properties adapted for incorporation in edible products and for enhanced rate of solubilization when reconstituted in aqueous solutions.

27. The method of making a calcium containing product according to claim 26, wherein the aqueous solution containing solubilized calcium attains the temperature between 130°F and 190°F.

28. The method of making a calcium containing product according to claim 26, wherein the aqueous solution containing solubilized calcium attains the temperature of at least 170°F.

29. The method of making a calcium containing product according to claim 26, wherein the temperature of the aqueous solution containing solubilized calcium is attained by an exothermic reaction taking place during the acidification of the aqueous slurry.

30. The method of making a calcium containing product according to claim 26, wherein the temperature of the aqueous solution containing solubilized calcium is attained by external heat applied during the acidification of the aqueous slurry.

31. The method of making a calcium containing product according to claim 26, wherein drying said aqueous solution containing solubilized calcium comprises a drying method selected from the group consisting of freeze drying, spray drying, tray drying and vacuum drying.

32. The method of making a calcium containing product according to claim 26, wherein drying said aqueous solution containing solubilized calcium comprises a freeze drying.

33. The method of making a calcium containing product according to claim 26, further comprising the step of:

adding ingredients to the aqueous solution containing solubilized calcium selected from the group consisting of sweeteners, flavors and colors.

34. The method of making a calcium containing product according to claim 26, wherein acidifying said aqueous slurry comprises mixing with the slurry at least one acid selected from the group consisting of lactic acid, malic acid, acetic acid, phosphoric acid, citric acid and ascorbic acid.

35. The method of making a calcium containing product according to claim 26, wherein said dried product is substantially amorphous.

36. The method of making a calcium containing product according to claim 26, wherein said dried product has a substantially non-dendritic morphology.

37. The method of making a calcium containing product according to claim 26, wherein said dried product further comprises potassium.

38. The method of making a calcium containing product according to claim 26, wherein said dried product further comprises zinc.

39. The method of making a calcium containing product according to claim 26, wherein said dried product is fiber-free.

40. The method of making a calcium containing product according to claim 26, wherein said reconstituted aqueous products do not form precipitates comprising calcium for at least six months.

41. The product made by the method of making a calcium containing product according to claim 26.

42. A liquid supplement comprising:
water; and
solubilized calcium,

wherein the solubilized calcium is provided by the product of claim 41.

43. The liquid supplement of claim 42, wherein said supplement further contains a mineral selected from the group consisting of potassium, magnesium and zinc.

44. The liquid supplement of claim 42, wherein the supplement comprises at least one ingredient selected from the group consisting of sweeteners, flavors and colors.

45. The liquid supplement of claim 42, wherein the supplement contains at least 250 milligrams of solubilized calcium per 8 fluid ounces of the supplement.

46. The liquid supplement of 42 claim, wherein the solubilized calcium is operative for remaining in solution in the supplement without precipitating therefrom for at least 6 months.

47. A method of making a calcium containing product for subsequent consumption, comprising:

making an aqueous slurry containing calcium;
acidifying said aqueous slurry to produce an aqueous solution containing solubilized calcium while attaining a temperature of at least 130°F; and
producing a dried product having an at least partially amorphous structure by drying said solution containing solubilized calcium.

48. The method of making a calcium containing product according to claim 47, wherein the aqueous solution containing solubilized calcium attains the temperature between 130°F and 190°F.

49. The method of making a calcium containing product according to claim 47, wherein the aqueous solution containing solubilized calcium attains the temperature of at least 170°F.

50. The method of making a calcium containing product according to claim 47, wherein the temperature of the aqueous solution containing solubilized calcium is attained by an exothermic reaction taking place during the acidification of the aqueous slurry.

51. The method of making a calcium containing product according to claim 47, wherein the temperature of the aqueous solution containing solubilized calcium is attained by external heat applied during the acidification of the aqueous slurry.

52. The method of making a calcium containing product according to claim 47, wherein drying said aqueous solution containing solubilized calcium comprises a drying method selected from the group consisting of freeze drying, spray drying, tray drying and vacuum drying.

53. The method of making a calcium containing product according to claim 47, wherein drying said aqueous solution containing solubilized calcium comprises a freeze drying.

54. The method of making a calcium containing product according to claim 47, further comprising the step of:

adding ingredients to the aqueous solution containing solubilized calcium selected from the group consisting of sweeteners, flavors and colors.

55. The method of making a calcium containing product according to claim 47, wherein acidifying said aqueous slurry comprises mixing with the slurry at least one acid selected from the group consisting of lactic acid, malic acid, acetic acid, phosphoric acid, citric acid and ascorbic acid.

56. The method of making a calcium containing product according to claim 47, wherein said dried product has a substantially non-dendritic morphology.

57. The product made by the method of making a calcium containing product comprising the steps of:

making an aqueous slurry containing calcium;

acidifying said aqueous slurry to produce an aqueous solution containing solubilized calcium while attaining a temperature of at least 130°F; and

producing an at least partially amorphous structure by drying said solution containing solubilized calcium to produce a dried product.

58. The product of claim 57, wherein the product further includes one or more sugars, sugar-substitutes or mixtures thereof.

59. A liquid supplement comprising water and solubilized calcium, wherein the solubilized calcium is provided by a product manufactured according to a method comprising the steps of:

making an aqueous slurry containing calcium;

acidifying said aqueous slurry to produce an aqueous solution containing solubilized calcium while attaining a temperature of at least 130°F; and

producing an at least partially amorphous structure by drying said solution containing solubilized calcium to produce a dried product.

60. The liquid supplement of claim 59, wherein the liquid supplement further comprises at least one sweetener.